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October 26, 2017

BY ECF

Hon. Valerie E. Caproni
U.S. District Court for the
Southern District of New York
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

RE: *Elysium Health, Inc. v. ChromaDex, Inc.*,
Case No. 17-CV-7394 (VEC)

Dear Judge Caproni:

Pursuant to the Court's Notice of Initial Pretrial Conference, dated October 3, 2017 (Dkt. 6), Plaintiff Elysium Health, Inc. ("Elysium") and Defendant ChromaDex, Inc. ("ChromaDex") jointly submit this letter and the enclosed Civil Case Management Plan and Scheduling Order for the Court's consideration.

Description of the Case, Claims and Defenses

Elysium's Statement of the Case and its Claims

This is an action for false advertising, trade libel, deceptive business practices and tortious interference with prospective economic relations. From 2014 until earlier this year, ChromaDex supplied the two active ingredients – nicotinamide riboside ("NR") and pterostilbene ("PT") – in Elysium's product, a dietary supplement called Basis. ChromaDex has now changed its business model to begin marketing products containing NR directly to customers. With this change from supplier to competitor came ChromaDex's improper conduct that forms the basis of this lawsuit.

On August 18, 2017, ChromaDex submitted a citizen petition (the "Sham Petition") to the Food & Drug Administration ("FDA"), purporting to request that FDA require Elysium to cease distributing Basis and take "other appropriate enforcement action." The Sham Petition, which ChromaDex disseminated widely, falsely claimed that Basis, which is now sourced from supply other than ChromaDex, is "contaminated" with the "toxic industrial solvent" toluene. ChromaDex also larded its filing with gratuitous and misleadingly positive statements about its own products. That ChromaDex filed the Sham Petition for the sole purpose of harming Elysium's reputation and business relationships is obvious on the face of the filing. In it, ChromaDex asks FDA to take "enforcement action," which is not within the scope of FDA's citizen petition procedures, as FDA has repeatedly stated, and as ChromaDex – which offers consulting services on FDA petitions – doubtless knows. Further, the Sham Petition falsely characterized Basis as "injurious to health" because it purportedly contains minute amounts of toluene, and misleadingly stated that FDA has not set any standards allowing for the inclusion of toluene in a dietary supplement. ChromaDex, however, failed to disclose in its Sham Petition that (1) it has sold products containing similar amounts of toluene, (2) FDA has adopted certain standards ("ICH Standards") for pharmaceuticals – and regularly accepts submissions from dietary supplement manufacturers applying those standards to nutritional supplements – that allow the presence of toluene in far greater quantities than the tiny amounts ChromaDex claimed to be present in Basis, and (3) ChromaDex has relied on those ICH Standards to attest to the safety of products it has sold as "food grade" and appropriate for inclusion in dietary supplements. These material omissions from the Sham Petition served to mislead the public about the safety of Elysium's Basis. As a result of ChromaDex's actions, Elysium has sustained damages including the loss of actual and potential customers, reputational harm, and the loss of existing and potential business relationships.

ChromaDex's pending Motion to Dismiss relies almost entirely on privileges unavailable to it. First, the Noerr-Pennington doctrine is inapposite here because, as alleged in the Complaint, the Sham Petition, knowingly brought pursuant to a process that would not provide the relief ChromaDex ostensibly requested and purporting to seek action in response to a supposed public health concern that ChromaDex itself knew to be nonexistent, was an objectively baseless effort to injure Elysium through use of the citizen petition process, rather than a sincere attempt to secure FDA action. *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus.*, 508 U.S. 49 (1993). Likewise, the litigation privilege has no application here because it does not cover false statements in connection with a proceeding that were made, like ChromaDex's were, solely for the purpose of injuring another party through subsequent dissemination. And because the Sham Petition was offered solely to undermine Elysium, it does not constitute speech protected by New York's Anti-

SLAPP statute. *Silvercorp Metals Inc. v. Anthion Mgmt. LLC*, 948 N.Y.S.2d 895 (N.Y. Cty. Sup. Ct. July 10, 2012).

ChromaDex's Statement of the Case and its Defenses

This is a frivolous lawsuit that should be dismissed because it stems from ChromaDex's exercise of its First Amendment right to petition a legislative agency to investigate a toxic chemical in Elysium's product. ChromaDex denies the factual allegations and innuendo in Elysium's complaint, but regardless, ChromaDex's Citizen Petition was completely protected speech under the *Noerr Pennington* doctrine, and does not fall under the very narrow "sham" exception to that broad immunity.

ChromaDex is the only known authorized supplier of the ingredient NR in the United States and invested many years and resources rigorously testing its NR for purity and safety. ChromDex's NR is sold under a New Dietary Ingredient Notification on file with the FDA, and it is also Generally Recognized As Safe ("GRAS") by the FDA. ChromaDex gave notice of non-renewal of its supply agreements with Elysium for both NR and PT after Elysium refused to pay for $3M of product ordered and further refused to constructively engage to resolve the dispute. When Elysium exhausted its legitimate supply of NR from ChromaDex, Elysium procured a new unknown source of NR for its consumer-facing product "Basis". ChromaDex tested samples of that new formulation, which revealed that Elysium's Basis now contains the toxic solvent Toluene, which is used in paint thinner and finger nail polish, and can cause serious cognitive, nervous system and brain damage with sustained use as recommended by Elysium. Elysium does not—and cannot-- deny that (1) Basis is now made with unknown ingredients not supplied by ChromaDex, (2) Basis now contains Toluene, (3) Elysium fails to disclose the presence of Toluene to consumers and (4) Toluene is toxic to humans. Elysium's only contention is that the *amount* of Toluene in Basis is not harmful to humans, which Elysium itself agrees is a determination that the FDA has never made with respect to dietary supplements. The ICH standards referenced by Plaintiff apply to pharmaceuticals, which are administered under medical supervision for short periods of time to treat serious disease, not dietary supplements that are consumed long term without supervision. ChromaDex appropriately filed its Citizen Petition to bring these serious health and safety issues to the attention of the FDA, requesting an investigation and if appropriate an enforcement action.

Elysium's lawsuit is an effort to chill ChromaDex's First Amendment rights to petition the federal government and voice its legitimate safety concerns to the FDA. The Petition is immunized from all of Elysium's claims by the *Noerr*-

Pennington Doctrine because, as even Elysium agrees, ChromaDex filed the Petition with the intent to ask the agency to exercise its discretion to enforce the law—specifically, the Food, Drug, and Cosmetic Act ("FDCA"). *See Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993). ChromaDex filed the Petition with objective probable cause, did not subjectively attempt to interfere with Elysium's business and the FDA encourages private parties to file citizen petitions with information that aids the FDA's enforcement decisions. *Apotex, Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59–62 (2d Cir. 2016). Elysium's disagreements with the substantive conclusions of the Petition do not, and cannot, make it a sham. *Id.*, 823 F.3d at 61. The Petition is also protected under the litigation privilege and New York's anti-SLAPP statute. The litigation privilege provides absolute immunity to complaints filed with the FDA. *Stega v. New York Downtown Hosp.*, 148 A.D.3d 21 (1st Dep't 2017). New York's anti-SLAPP law shields from liability petitioners who speak publicly on a matter related to the plaintiff's government-granted permission, in this case Elysium's representations that the safety of Basis is blessed by the FDA. *Silvercorp Metals Inc. v. Anthion Mgmt. LLC*, 948 N.Y.S.2d 895 (2012).

Contemplated Motions

Elysium presently does not contemplate filing any motions with the Court. On October 19, 2017, ChromaDex filed a Motion to Dismiss Elysium's Complaint under the *Noerr-Pennington* Doctrine, the litigation privilege, and New York's Anti-SLAPP statute, and for failure to state a claim under Fed. R. Civ. P. 12(b)(6).

Basis for Subject Matter Jurisdiction

This Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331 and 15 U.S.C. § 1121[1] over Count I (violation of Section 43(a) of the Lanham Act) because it arises under 15 U.S.C. § 1125. Diversity jurisdiction exists over Elysium's remaining claims pursuant to 28 U.S.C. § 1332 because this is an action between citizens of different states[2] and the amount in controversy exceeds $75,000 exclusive of interests and costs.

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[1] The Complaint incorrectly cites the jurisdictional statute associated with the Lanham Act as 28 U.S.C. § 1121.

[2] Elysium is incorporated in Delaware and maintains its principal place of business in New York. ChromaDex is incorporated in and maintains its principal place of business in California.

Notice of Related Case

On October 25, 2017 ChromaDex filed a lawsuit against Elysium in the U.S. District Court for the Southern District of New York, Case No. 1:17-cv-08239, for false and deceptive advertising, deceptive trade practices, and unfair competition, based on Elysium's alleged misrepresentations regarding the safety and purity of its Basis product and about approval by the FDA. ChromaDex believes this case should be heard by the same court.

Prospect for Settlement

Elysium and ChromaDex have other disputes outside the scope of this litigation that also require resolution. The parties are unable at this time to determine the likelihood of settlement, but have committed to engage in good faith efforts to resolve their disputes. Because the issues between them are broader than those raised in this litigation, the parties believe a direct dialogue may be productive, but both parties are willing to participate in this Court's mediation program.

Civil Case Management Plan

The parties enclose with this letter a proposed Civil Case Management Plan and Scheduling Order. ChromaDex proposes staying Initial Disclosures and discovery pending a ruling on its Motion to Dismiss, which it asserts would further permit the Related Case to catch up if the Motion to Dismiss is not granted. Absent a stay, ChromaDex proposes a fact discovery cut-off of 180 days from the date of the Initial Pretrial Conference with the expert discovery cut-off 30 days thereafter. Elysium opposes a stay pending a ruling on ChromaDex's Motion to Dismiss, and believes no unique complexities or exceptional circumstances exist in this case to warrant departure from the 90-day fact discovery deadline set forth in the Court's form Case Management Plan and Scheduling Order. Solely to avoid burdening the Court with unnecessary disputes, however, Elysium offered to split the difference with ChromaDex and propose to the Court a fact discovery deadline of 135 days after the Initial Pretrial Conference on November 3, 2017. ChromaDex rejected that proposal. Elysium joins ChromaDex's proposal to set the expert discovery cut-off 30 days after the fact discovery deadline.

The parties look forward to discussing these matters with the Court.

Respectfully submitted,

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